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Safety Data Sheet according to HPR, Schedule 1

Printing date 10/16/2020 Reviewed on 10/16/2020

1 Identification

· Product identifier

· Product name: rac N-Desmethyl Tramadol-d3 Hydrochloride

· Part number: TRC-D294702

· CAS Number: 1261398-09-7

· Application of the substance / the mixture Reference material for laboratory use only

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

VHG LGC Standards 276 Abby Road Manchester, NH 03103 UNITED STATES OF AMERICA

· Information department:

Product safety department

eMail: sds-request@lgcgroup.com

 $\cdot \textit{Emergency telephone number:}$

For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

2 Hazard identification

· Classification of the substance or mixture



GHS07

Acute Toxicity (Oral) - Category 4 H302 Harmful if swallowed.

Acute Toxicity (Dermal) – Category 4 H312 Harmful in contact with skin.

Acute Toxicity (Inhalation) - Category 4 H332 Harmful if inhaled.

Specific Target Organ Toxicity - Single Exposure - H336 May cause drowsiness or dizziness.

Category 3

· Label elements

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



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- · Signal word Warning
- · Hazard statements

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.

H336 May cause drowsiness or dizziness.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P322 Specific measures (see on this label).

P361 Take off immediately all contaminated clothing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 2 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 2 Fire = 0

0 Fire = 0

REACTIVITY 0 Reactivity = 0

3 Composition/Information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description

1261398-09-7 rac N-Desmethyl Tramadol-d3 Hydrochloride

- · Identification number(s) -
- · RTECS: -
- · Additional information:

This product has been isotopically labelled with deuterium, a stable isotope of hydrogen.

4 First aid measures

- · Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

Seek medical treatment.

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· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing:

Rinse mouth. Do not induce vomiting.

Seek medical treatment.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · Advice for firefighters
- · Protective equipment:

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

6 Accidental release measures

- $\cdot \textit{Personal precautions, protective equipment and emergency procedures} \ A \textit{void formation of dust}.$
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Ensure adequate ventilation.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Thorough dedusting.

Store in cool, dry place in tightly closed receptacles.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:

Please refer to the manufacturers certificate for specific storage and transport temperature conditions.

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Store only in the original receptacle unless other advice is given on the CoA.

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.

- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: Keep receptacle tightly sealed.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/ Personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

- · Material of gloves Nitrile rubber, NBR
- · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Solid
Color: Off white
Odor: Odorless

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Product name: rac N-Desmethyl Tramadol-d3 Hydrochloride

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· Odor threshold:	Not determined.	
· pH-value:	Not applicable.	
· Change in condition		
Melting point/Melting range:	86-95 °C	
Boiling point/Boiling range:	Not determined.	
· Flash point:	Not applicable.	
· Flammability (solid, gaseous):	Not determined.	
· Ignition temperature:	Not determined	
Decomposition temperature:	Not determined.	
· Auto igniting:	Not determined.	
· Danger of explosion:	Not determined.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
Density:	Not determined.	
· Relative density	Not determined.	
· Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Not determined.	
Partition coefficient (n-octanol/wate	r): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Other information	No further relevant information available.	

10 Stability and reactivity

· Reactivity

Stable under normal conditions.

No further relevant information available.

- · Chemical stability Stable under normal conditions.
- · Thermal decomposition / conditions to be avoided:

Formation of toxic gases is possible during heating or in case of fire.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid Heat.
- · Incompatible materials: Strong oxidizing agents.

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· Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: Based on available data, the classification criteria are not met.
- · on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- $\cdot \textit{Bioaccumulative potential No further relevant information available}.$
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Dispose in accordance with national regulations.

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UN-Number		
DOT/TDG, ADR, IMDG, IATA	Not applicable	
DOT/TDG, ADR, IMDG, IATA	Not applicable	
Transport hazard class(es)		
DOT, ADR, ADN, IMDG, IATA		
Class	Not applicable	
Packing group		
DOT/TDG, ADR, IMDG, IATA	Not applicable	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex	II of	
MARPOL73/78 and the IBC Code	Not applicable.	
WARPOL/3//8 and the IBC Code UN "Model Regulation":	Not applicable Not applicable	

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- $\cdot \textit{Sara}$
- · Section 355 (extremely hazardous substances): Substance is not listed.
- · Section 313 (Specific toxic chemical listings): Substance is not listed.
- · TSCA (Toxic Substances Control Act): Substance is not listed.
- · Canadian substance listings:
- · Canadian Domestic Substances List (DSL) Substance is not listed.
- · Canadian Ingredient Disclosure list (limit 0.1%) Substance is not listed.
- · Canadian Ingredient Disclosure list (limit 1%) Substance is not listed.
- · Hazard pictograms



- · Signal word Warning
- · Hazard statements

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.

H336 May cause drowsiness or dizziness.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

 $P280 \ Wear \ protective \ gloves/protective \ clothing/eye \ protection/face \ protection.$

P322 Specific measures (see on this label).

P361 Take off immediately all contaminated clothing.

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P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI) disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

- Date of the latest revision of the safety data sheet 10/16/2020 / -
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· Data compared to the previous version altered. All sections have been updated.

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